

## Initiating Coverage

## Overview:

<b>Industry:</b>	Biotechnology
<b>Country:</b>	Sweden
<b>Primary Exchange:</b>	Nasdaq OMX
<b>Symbol:</b>	<b>OASM.SE</b>
<b>Reuters:</b>	OASM.ST
<b>Secondary Exchange</b>	Frankfurt
<b>Symbol:</b>	<b>OMAX.DE</b>
<b>Reuters:</b>	OASM.DE
<b>WKN:</b>	509722
<b>ISIN</b>	SE0000722365
<b>Website:</b>	oasmia.com

<b>Current Price:</b>	1.15
	<b>High      Low</b>
<b>Price 52W.:</b>	1.93      1.13
<b>Market Cap. (Mill. EUR)</b>	62.6
<b>No. Of Shares (in Mill.)</b>	52.1

## Shareholders

<b>Freefloat</b>	<b>40.0%</b>
<b>Alceco S.A.</b>	<b>55.7%</b>
<b>Avanza Bank Holding AB</b>	<b>4.3%</b>

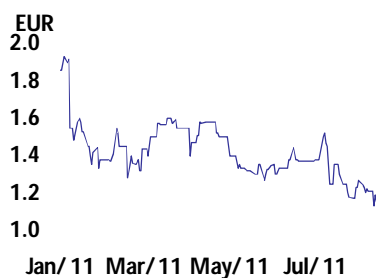
## Performance

<b>4 Weeks</b>	-11.5%
<b>13 Weeks</b>	-12.9%
<b>26 Weeks</b>	-20.7%
<b>YTD</b>	-39.5%

## Next Newsflow:

<b>Paclical EMA filing</b>	Q4 2011/12
<b>Paccal Vet FDA and EMA approval</b>	Q4 2011/12
<b>Complete enrollment for Paclical Phase III</b>	H2 2011/12
<b>Closure of partnership deals for Paclical</b>	H2 2011/12

## 52-Week Price history



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## Oasmia Pharmaceutical AB

## Nanotechnology Innovations in Cancer

- Oasmia Pharmaceutical has developed a nanotechnology based technology to deliver the most common and effective chemotherapies with greatly reduced side effects and improved dosing. Oasmia's lead product, Paclical is in Phase III trials for ovarian cancer. The company will file with the EMA by the end of the year. We anticipate EMA approval during 2012/13.
- We estimate peak sales potential of €600m for Paclical in ovarian cancer. The company will pursue additional indications in the near term. Further approvals would increase sales potential exponentially and the drug would be likely to reach blockbuster status.
- Oasmia is also developing formulations for the underserved market of canine oncology. With the number of companion animals and amount spent on veterinary care increasing each year, animal health is an increasingly attractive market. Oasmia has submitted its lead animal health product, Paccal Vet to the FDA and FDA and is awaiting approval. The product is already partnered for the major markets of the US, Canada, Europe and Japan. We estimate peak sales at €500m.
- Oasmia completed a €25m capital raise during 2010, putting the company in a strong position to complete commercialization, commence production, and launch the therapies onto the market. The company reported cash of €2.2m on 31.7.2011. This will be boosted by roughly €5.5m in milestones on the approval of Paccal Vet. We anticipate cash to be further enhanced by the company closing additional partnership deals primarily for Paclical and also for Paccal Vet over the next 18 months.
- We believe Oasmia Pharmaceutical is undervalued for a company with a product in Phase III development. We anticipate the share price to increase over the coming year by news flow related to regulatory filings and initiation of trials for additional indications. As the company approaches commercialization, the risk of development will fade away and the value of the company will accordingly rise. We initiate coverage with a Buy rating and a €1.87 price target.

## Key Pipeline Products

Indication	Current Phase of Development	Expected Registration	Development Costs	Partnership status	Estimated peak sales
<b>Paclical</b>					
Ovarian Cancer	Phase III	2012	€-15m	Partially Partnered	€600m
Other tumors	Proof of Concept	2016	€0-12m	Not partnered	>€1000m
<b>Paccal Vet</b>					
Canine Skin Cancers	Registration	2011/12	€-4m	Partnered	€600m
<b>Doxophos Vet</b>					
Canine Lymphoma	Phase I	2016	€-10m	Unpartnered	€600m

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## 1. INVESTMENT CASE

### **IMMINENT FILING FOR INNOVATIVE CANCER THERAPY**

Oasmia's lead product is in clinical trials for ovarian cancer. The company recently released interim results for its Phase III trial demonstrating that the therapy is at least as effective as paclitaxel, the most commonly used therapy in ovarian cancer. The company is using this data to file for EMA regulatory approval. We anticipate submission by the end of the year and marketing approval by the end of 2012.

### **NOVEL NANOTECHNOLOGY THERAPY WITH EXCELLENT SAFETY PROFILE**

Paclical is a new and safer formulation of a chemotherapy agent that has been on the market since the 1980s. Paclitaxel, the active drug, in Paclical is a well characterized drug with an excellent efficacy. Drug delivery of paclitaxel, however, is a challenge. Current methods cause a number of side effects including allergic reaction, loss of white blood cells, neurotoxicity and it may contribute to drug resistance. Paclical utilizes nanotechnology to overcome these challenges. This new formulation of a well known drug allows the company to take advantage of the attractive market for novel oncology products without exposure to the risks and uncertainties involved in developing a completely novel therapy.

### **BLOCKBUSTER POTENTIAL WITH ADDITIONAL INDICATIONS**

Paclical is currently in development for the indication of ovarian cancer which is a smaller indication than many other types of cancer. Oasmia will likely pursue additional approvals. Each additional approval will lead to an exponential growth in sales potential. If multiple approvals are granted, Paclical could achieve blockbuster status.

### **EXPLOITING THE ATTRACTIVE CANINE ONCOLOGY MARKET**

Cancer is the leading cause of death among dogs. As veterinarians offer ever more sophisticated treatments once reserved for humans, pet owners are increasingly willing to treat their companion animals' medical conditions. This trend is compounded by the growing prevalence of pet insurance making these treatments more affordable to pet owners. Oasmia is in a position to take advantage of these trends by developing one of the first oncology therapies to show proven efficacy in dogs

### **ESTABLISHED PARTNERSHIPS PROVIDE SECURITY OVER CASH FLOWS.**

Oasmia has closed a number of partnerships for both Paccal Vet and Paclical. Paccal Vet is partnered with Abbott Laboratories in the US and Canada, Orion Corporation in Europe and Nippon Zenyaku Kogyo in Japan. Paclical is partnered with Medison Pharma in Turkey and Israel. The company has access to payments totaling roughly €24.2m on achievement of regulatory and commercial milestones.

## 2. SWOT-ANALYSIS

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>- The oncology market is an attractive segment of drug development with drugs approved for multiple indications reaching blockbuster status.</li> <li>- Canine oncology is an underpenetrated and growing market. The company will face a larger market with very little competition</li> <li>- Oasmia's products are in late stage development. It has completed interim analysis of the Phase III trial and is preparing submission to the EMA.</li> <li>- The company successfully completed a capital raise of nearly €25m in 2010 and is cash secure to bring its products through clinical development</li> </ul>	<ul style="list-style-type: none"> <li>- Ovarian cancer is one of the smaller oncologic indications and Oasmia's revenues may initially be limited by an approval solely for this indication.</li> <li>- The company is preparing to submit for EMA filing, but the FDA will require additional data related to progression free survival. This data may take years to acquire.</li> <li>- As a European based company, Oasmia may find it difficult to close partnership deals in and fully penetrate the US market.</li> <li>- With no products on the market, the company does not have sustainable cash flows</li> <li>- There is low liquidity in the german share listing due to lack of investor awareness.</li> </ul>
Opportunities	Threats
<ul style="list-style-type: none"> <li>- Increasing penetration of the pet insurance market makes it much more likely that pet owners will opt to treat cancers than euthanize their companion animals.</li> <li>- Paclical is likely to be an effective therapy in additional indications for which paclitaxel is approved: breast, lung, and Kaposi syndrome. Further approvals would increase sales potential exponentially.</li> <li>- Oasmia's XR-17 technology platform can be utilised to develop multiple drugs. Additional pipeline therapies include conjugates of docetaxel and doxorubicin.</li> </ul>	<ul style="list-style-type: none"> <li>- Paclical faces competition from Abraxane, an albumin-bound formulation of paclitaxel. Abraxane was approved for second line breast cancer in 2005 and is in trials for additional indications including ovarian cancer.</li> <li>- Endocyte Inc is also developing a similar drug, EC145 for ovarian cancer. The drug will not initially be approved as a first line treatment, but may compete directly with Paclical in the future.</li> <li>- Risk averse financial markets may push share prices downward due to factors beyond the control of Oasmia's management.</li> </ul>

### 3. RISK ANALYSIS

#### PIPELINE

The company is a development stage company. Therefore the value of the company lays in future revenue streams which will be realized as pipeline drugs acquire approval. Failure to gain approval or delays in the process would decrease or delay future revenues and milestone payments. In addition, there is uncertainty as to whether research and development expenditure will result in approvals and subsequent revenue.

#### REGULATORY

The company will require EMA approval to market its therapies in Europe, FDA approval to market its therapies in the US, and additional to market its therapies in other countries. Failure to achieve approvals or delays in the process will result in an increase in costs and a delay in revenues. Any changes to the regulatory process requiring more extensive clinical trials or data analysis may also increase the costs or timings associated with development.

#### MANUFACTURING

Oasmia will initially manufacture its products itself in the company's cGMP (approved for making clinical grade products) facility. The company therefore faces risks associated with manufacturing. If the company were to lose its cGMP designation it would not be allowed to produce medicinal products. Machinery malfunctions or supply chain disruptions could prevent the company from manufacturing and delivering products to its partner companies and customers. This could lead to a loss of revenues or increase in costs.

#### LIQUIDITY

As a development stage company, the company is largely dependent on financing through equity, partnership deals, and debt until drugs are approved, marketed, and begin to provide positive cash flows. Failure to secure financing will prevent the company from continuing operations. Increased expenditure due to regulatory delay or other unforeseen expenses may require further equity financing which could lead to dilution.

#### MARKET

Once approval is granted, Oasmia or its partner companies must first negotiate reimbursement prices with national bodies and insurance policies. Negotiated reimbursement price will significantly affect future revenues. The company may face competition from existing or future therapies. Commercialization of therapies will require effective sales and marketing. This will be the responsibility of Oasmia's partners. Partner companies may not prioritize Oasmia's products preventing them from achieving a desired level of market penetration. Additionally, partnership companies may not have a sufficient sales force or marketing strategy to achieve penetration. This could negatively impact future revenues.

#### EXCHANGE RATE

Oasmia's reporting currency is Swedish Kroner. Revenues from partner companies are denominated largely in Euros and US Dollars. The company has both cash inflows and outflows denominated in foreign currencies resulting in some natural hedging which mitigates this risk. However, volatility in exchange rates could significantly affect financial statements.

## 4. VALUATION

### SUM OF PARTS PIPELINE VALUATION

We have used a sum of parts valuation for Oasmia Pharmaceutical AB. Discounted cash flow valuations are inherently invalid for companies in a development stage. DCF valuations fail account for the uncertainty regarding the timing and value of cash inflows and outflows. In addition, in biopharmaceutical development many of the cash inflows and outflows are one-offs with limited predictive value for the future. Clinical development is divided into discreet stages at which a company may continue development if successful or halt an unsuccessful development program. Thus, a real options methodology is most appropriate to reflect this flexibility in future expenditures and cash flows. The overall value of the company is thus the sum of the individual projects and liquid assets.

### ACCOUNTING FOR RISK

This valuation methodology is conservative as it accounts for risk in multiple ways. This derives a conservative valuation with significant upside potential. We believe this method is most appropriate for development stage companies.

Firstly, we have only included clinical stage products nearing approval in our valuation. Oasmia has two additional products in development: Doxophos and Docecal. These products are in development for both human health and animal health formulations. These products are likely to contribute value to the company, but have not been included in our valuation due to their early stage.

Second, we have performed a valuation only until the year 2035 and have not calculated any residual value for the company. This reflects the uncertainty surrounding competing products and technologies that may be developed and approved over the next 25 years. This also reflects the loss of revenues Oasmia will face one products lose their patent protection.

Revenues and cash flows have been discounted using a relatively high WACC. This represents the uncertainty involved in development and commercialization of pharmaceutical products. The WACC has been calculated by taking into account company specific risk factors. For a development stage biopharmaceutical company such as Oasmia Pharmaceutical, this includes the stage of development, the novelty and riskiness inherent in the product, the company's imminent cash needs, likelihood of dilution, and historical share price performance. For Oasmia, we have calculated a WACC of 18.3%.

Finally, we have adjusted cash flows for the probability that they will transition between phases of drug development and continue development. These probabilities are based on published research, but adjusted to reflect our view of the likelihood of success of individual products. Oasmia's products have a greater chance of success than other products in development because it is a novel formulation of a well characterized drug that has previously demonstrated very good efficacy and safety.

### COSTS AND TIMING

Development costs and timings have been estimated by a combination of discussions with Oasmia's management, review of historical research and development expenses, and consideration of norms for regulatory costs and timelines. We have assumed regulatory filing processes will take 12 months and once approval is granted, it will be a further 12 months

before the product is launched on the market. This model therefore provides significant leeway for any delays that occur during development and the filing process.

### **REVENUE FORECASTS**

Oasmia has closed a number of partnership deals for Paclical and Paccal Vet. We have included the milestone payments related to these deals in our valuations. Additionally, we have forecast upfront and milestone payments on partnership deals by comparing these to similar deals closed in oncology therapies over the past two years.

Sales have been forecast using a patient model estimating the number of patients with the approved indication and the percentage of these patients using the therapy once on the market. We have included sales from Europe, the US and Russia as this reflects the major partnership deals that Oasmia has in place or is seeking. The products are likely to gain approval and be sold in additional areas of the world. Additional rest of world sales has not been included in our valuation and would be a further source of upside.

We have assumed tiered royalties ranging from 20-30%. This is below the company's forecasts of 25-30%. The majority of partnership deals we have reviewed include tiered royalties starting at 15%. We believe Oasmia is likely to be able to negotiate higher royalties due to its late stage of development, but have chosen to be more conservative in our model.

We have additionally estimated a gross profit margin to account for manufacturing costs. We have additionally forecast an EBIT margin to account for general administrative and management costs. We have assumed the company will have tax losses carried forward or additional write-offs for research and development expenses while developing additional pipeline products. We have forecast an effective tax rate starting at 10% in 2020 and growing to 30% as the company becomes fully commercialized and ceases research and development activities.

### **PATENT LIFE**

Oasmia's products have patent protection until 2023 and the company has applied for extension until 2028. Due to the highly technical nature of the company's technology, the products will be difficult to replicate without specific know-how. This may insulate the company from generic competition even in the absence of patent protection. We have reflected this by including these revenues in our model, but adjusting the probability that Oasmia will achieve these sales.

### **ADDITIONAL INDICATIONS**

Our valuations have been based only on products and indications currently in clinical development. We would envision further trials for additional indications to be carried out by Oasmia alone or in cooperation with its partners. However, the timing and probability of further trials will be dependent on the success of initial indication and the development priorities of the partner company. We have therefore chosen not to include any further indications in our valuation model. Sales would likely grow exponentially as more indications are approved, thus for successful therapies, this could provide significant upside potential.

### **CONSERVATIVE VALUATION WITH UPSIDE POTENTIAL**

A sum of parts methodology therefore provides a more appropriate valuation of a development stage company than forecasting financial statements. From our valuation, we derive a fair market capitalization of €7.6m and a fair value per share of €1.87. This value will be boosted as the company achieves clinical and regulatory milestones as this will increase success probabilities in our valuation.

We have also included dilution related to potential share issues through the Standby Equity Distribution Agreement (SEDA) that Oasmia has in place. We have assumed €3.5m in SEDA funding and concomitant dilution of 3.1m shares. However, this dilution has been accounted for with the treasury stock method, and therefore has a limited impact on price per share. We believe the company will be able to secure the partnerships and approvals necessary to secure cash flows without SEDA financing. We have, however, taken a conservative view for the purposes of our valuation and included dilution related to potential SEDA financing.

Sum of parts	€'000	% of Fair Value
Paclical	48,580	50%
Paccal Vet	46,793	48%
Plus cash/less debt	2,200	2%
<b>Market cap (€'000)</b>	<b>97,572</b>	
Current number of shares ('000)	52,079	
New share issues ('000)	155	
Diluted number of shares ('000)	52,234	
<b>Price per share</b>	<b>1.87</b>	

#### Lead Product: Paclical

Paclical is in development for ovarian cancer. It has orphan drug designation with the FDA and EMA. Orphan drug designation allows the company to receive protocol assistance and market exclusivity for ten years in Europe and seven in the US. Oasmia's access to protocol assistance and previously published clinical trial data on Paclical lead us to believe this product has a very high probability of success. We anticipate the company closing partnership deals for licensing and distribution across Europe and the US within the next three years. We have assumed EMA approval during the year ending 30.4.2013 and FDA approval during the year ending 30.4.2016. We have also assumed a further €5m in development costs prior to FDA approval and additional partnership deals resulting in upfront and milestone payments totaling €28m.

Year ending 30.4	Phase of Development	Cash Inflows/ (outflows)	Present Value	Probability of Success	Aggregate Probability	Adjusted PV
2012-2014	Phase III	(17,000)	(13,123)	80%	80%	(10,499)
2012-2013	Upfront and Milestone Payments	14,200	18,444	65%	52%	9,591
2013-2023	Royalties during patent life	406,242	99,322	85%	44%	43,900
2023-2028	Royalties during patent extension	232,228	19,879	60%	27%	5,272
2028-2035	Royalties after patent life	61,866	2,379	50%	13%	315
<b>Paclical Fair Value</b>						<b>48,580</b>

#### Animal Health: Paccal Vet

In 2010 Oasmia submitted the registration for Paccal Vet dossier to the FDA in canine mast cell tumors. The company is now awaiting approval. Oasmia already has partnerships in place for Paccal Vet. The company is partnered with Orion Corporation in Europe, Abbott Laboratories in the USA and Canada and Nippon Zenyaku Kogyo in Japan. We have included anticipated milestone payments totaling €19.3m from these partnership deals in our valuation. We have estimated the number of dogs in the US, Europe and Japan that will suffer from tumors that could be treated by Paccal Vet. From this we have assumed initially 10% of these dogs will receive treatment and this percentage will grow over time to 20% as pet insurance policies increase. We have then estimated the percentage of these dogs that will be treated with Paccal Vet. We believe this leads to a conservative valuation of Paccal Vet.



**Veterinary indication: Paccal Vet**

Year ending 30.4	Phase of Development	Cash Inflows/ (outflows)	Present Value	Probability of Success	Aggregate Probability	Adjusted PV
2016-2016	Research and Development Costs	(4,500)	(3,450)	100%	100%	(3,450)
2016-2025	Milestone Payments	19,728	7,109	85%	85%	6,043
2013-2023	Royalties during patent life	314,576	79,743	65%	55%	44,058
2023-2028	Royalties during patent extension	103,086	9,272	60%	33%	3,074
2028-2035	Royalties after patent life	21,882	858	50%	17%	142
<b>Paccal Vet Fair Value</b>						<b>46,793</b>

**Additional Products: Doxophos and Docecal**

Oasmia has two additional products it is developing, Doxophos and Docecal. Both of these products will be developed for both human and animal health indications. Doxophos Vet is in Phase I trials for canine lymphoma. As these products are at such an early stage in development, we chosen not to include them in our valuation. These products thus provide upside potential as they will boost the value of the company as their development pathway becomes focused.

**5. FINANCIAL POSITION****LIQUIDITY**

At 31.7.2011, the company reported cash of €2.2m. In addition, the company has access to a credit line of 45MSEK (€5.0m). With no other sources of income, the current funding will be sufficient through December, 2011. On FDA and EMA approval of Paccal Vet, the company will receive €5.5m in milestone payments from partner companies. Oasmia is also looking to close additional partnerships in the coming months. The company will receive upfront payments on the closure of these deals. Once these deals are in place, we expect the company's cash flows to be secure until Paccal Vet is launched onto the market and royalty revenues begin to sustain the company.

**EQUITY**

Oasmia successfully completed a share issue in 2010. It raised roughly €25M (239MSEK) by issuing 14.5m shares at SEK 16.5 (€1.81) per share. The company had a total of 52.1m shares outstanding at year end. Oasmia has a standby equity distribution agreement (SEDA) in place for 75MSEK (€8.2M). The SEDA gives the company the option, but not the obligation to acquire additional funding by issuing shares in tranche in exchange for cash. If the regulatory approval of Paccal Vet is delayed, and the company fails to secure additional partnership deals for Paccal, SEDA funding may be required. This equity instrument provides additional security over liquidity, but pulling funds from the SEDA would result in additional shares being issued. This would cause dilution for the shareholders, and would also impact volatility of the share.

**CASH FLOWS**

Oasmia's operation and investing cash outflows peaked in the year ending 30.4.2011 due to both the Phase III Paclical trial and the preparations for launching Paccal Vet. Phase III is the most expensive clinical development phase and the majority of the costs are incurred in the initiation of the trial. Oasmia has completed interim analysis and is nearing full enrollment for the trial, thus costs associated with the trial will begin to taper off. The company anticipates a monthly cash burn of €1.3m going forward.

## 6. OASMIA'S NANOTECHNOLOGY PIPELINE

### CYTOSTATICS FOR ONCOLOGY THERAPIES

One of the most effective strategies for treating cancer is with cytostatics. These drugs act by preventing cell division. Thus, for rapidly dividing cancer cells, drugs can prevent this cell division are extremely effective in treating these tumors and preventing them from growing. Taxanes are a group of these drugs that are cytostatic that include paclitaxel (Taxol) and docetaxel (Taxotere).

### PACLITAXEL

Paclitaxel is approved for breast, lung, and ovarian cancer and AIDS related Kaposi syndrome. The drug is derived from the bark of the Yew tree. It was discovered in the 1960s. But its use as a drug was delayed until the 1980s because it is not water soluble, and therefore very difficult to administer as a drug.

To overcome the problem of delivery, paclitaxel must be injected to a patient in a solution of polyethoxylated castor oil (Cremaphor EL). Cremaphor EL is used to deliver a wide variety of drugs, but the chemical properties of paclitaxel require it to be used in much higher quantities.

The majority of patients experience an allergic reaction to Cremaphor EL. To prevent this, patients are premedicated with high dose corticosteroids. Other adverse events include the loss of white blood cells and damage to nerve cells. It has also been suggested that Cremaphor EL contributes to drug resistance.

In spite of premedication, as many as 44% of patients experience allergic reactions and 1.5 to 3% of these patients' reactions are so severe they must discontinue treatments. One study showed grade 2 or 3 neurotoxicity occurring as a result of paclitaxel combined with cisplatin in 13% of patients and grade 3-4 in 18% of patients.

It is widely accepted that Cremaphor EL is a necessary evil, but there are currently no other alternatives to deliver Paclitaxel. And paclitaxel has such efficacy that doctors and patients are willing to endure the risks. The amount of paclitaxel that doctors are able to administer has thus far been limited to that which can be dissolved in a non-toxic dose of Cremaphor EL solution. Thus eliminating this solution should lead to not only fewer adverse events, but also improved efficacy.

### Computer Generated Model of a Paclitaxel Molecule

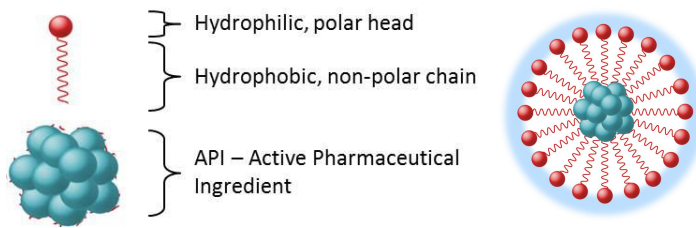


### XR-17: A SOLUTION TO DRUG DELIVERY

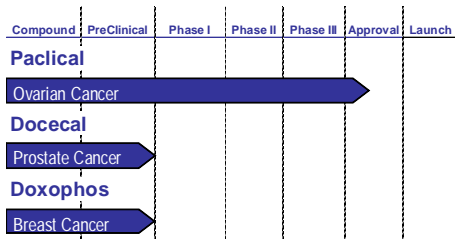
Oasmia has developed a technology that allows the delivery of taxane drugs without the need for Cremaphor EL or other harmful solutions. XR-17 is non-toxic and encapsulates the active ingredient and allows it to be dissolved in a water solution, such as saline. The company is using this technology to develop Paclical and Paccal Vet with paclitaxel as the active compound, as

well as Docecal and Docecal Vet with docetaxel as the active compound, and Doxophos and Doxophos Vet with doxorubicin as the active compound.

### XR-17 Creates a Water Soluble Micelle Containing the Drug for Easy Delivery



## 6.1. Human medicine



### PACLICAL

Oasmia recently published top line data from the interim analysis of their Phase III trial for Paclical. The company is using the results from the interim analysis to submit their EMA filing. The study, involving 80 clinics in 16 European countries will enroll a total of 650 patients. The interim analysis was based on 400 of the participants. The results demonstrate that Paclical is as effective as Taxol. Due to the properties of Paclical, it is possible to deliver a higher dose of the medicine over a shorter infusion time without premedication with high dose corticosteroids. Paclical was delivered via 1 hour intravenous infusion, while Taxol is delivered over 3 hours. 175mg/ml of Taxol was delivered over a 3 hour infusion, while 250 mg/ml of Paclical was delivered over a 1 hour infusion.

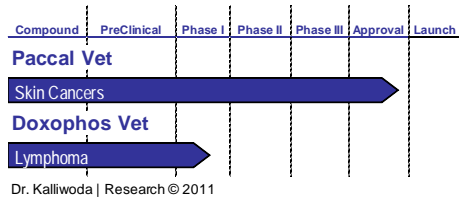
This data is being used to support an EMA regulatory filing. The study is anticipated to Oasmia is filing their first submission in ovarian cancer. As the mechanism of action is similar in all of paclitaxel's approved therapies, it is likely that Paclical will be effective in a number of other indications. This would require additional clinical trials in these indications.

Oasmia's phase III clinical trial, which has been designed with protocol assistance from the EMA, uses a novel biomarker of ovarian cancer that can be measured in blood. This allows collection of substantially more data at a greater number of time points. Oasmia therefore gains a better picture of the response of tumors to Paclical. This is in contrast to imaging studies where the tumor is measured at, for example, 2 or 3 time points. A tumor may initially respond to treatment and then become resistant to a treatment. If this change happened between two data point collections, this would not be captured as a tumor response to a treatment.

### DOXOPHOS AND DOCECAL

The company has an approval to initiate Phase I trials of Docecal in the Baltic States and Russia. The company is pursuing an initial indication of prostate cancer. Doxophos is in preclinical development.

## 6.2. Animal medicine



### PACCAL VET

Oasmia filed registration for Paccal Vet in August 2010 for mastocytoma in dogs. Oasmia has received minor use designation from the FDA for Paccal Vet for the treatment of squamous cell carcinoma. Minor use designation is similar to orphan drug status for human medicines. The designation makes Paccal Vet eligible for a conditional use approval. This allows the drug to be marketed for up to 5 years once safety has been demonstrated, while the company continues to carry out trials and collect efficacy data. In addition, minor use designation provides market exclusivity for 7 years following approval. The company is awaiting approval for Paccal Vet. We anticipate this approval will be granted in the coming months.

### DOXOPHOS VET

Oasmia has initiated a Phase I study in Germany and Austria for canine lymphoma.

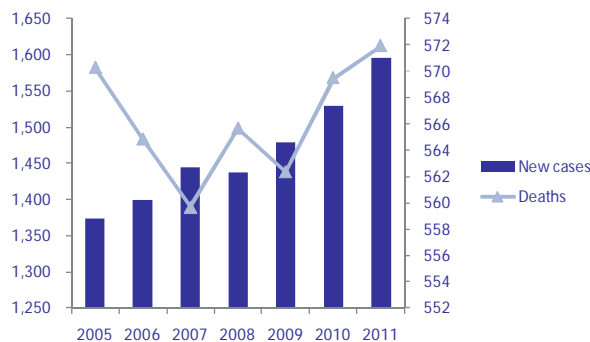
## 7. MARKET ANALYSIS

### 7.1. Human medicine

#### THE MARKET FOR ONCOLOGY THERAPIES

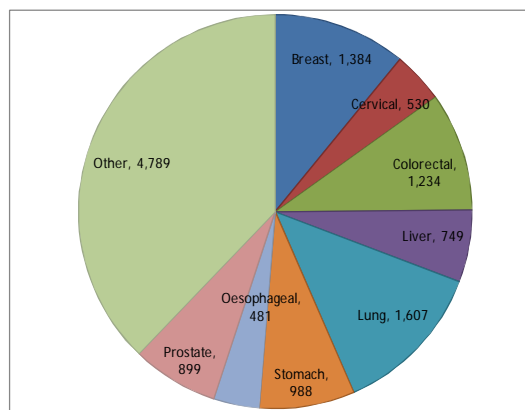
According to the World Health Organization (WHO), cancer is the leading cause of death worldwide and the number of global cancer deaths is projected to increase to 11.5m deaths in 2030. The risk of getting cancer before age 75 is 18.7% and the risk of dying in 11.2%. According to the American Cancer Society, the estimated number of new cases of cancer has grown an average of 2.7% per year since 2005. And though progress has been made to offer increasingly better treatments, the number of deaths continues to increase. With 5 year survival rates for a number of cancers less than 10%, and cancer patients often enduring a difficult battle with therapies that are insufficiently effective or have poor side effect profiles, there is no question that better therapies are needed. As a result, there is not only a growing market for oncology therapies, but there is also a great need for innovative drugs with greater efficacy and safety.

**New Cancer Cases and Deaths in the US per Year ('000)**



Oncology therapies with broad approvals in a wide range of therapies often achieve blockbuster status (Sales >\$1m). Initial regulatory approvals are limited to only the types of cancer in which efficacy has been demonstrated. Further approvals require additional clinical trials.

**Worldwide Incidence of Cancer per Type**



Furthermore, as many of the molecular mechanisms of different cancers are similar, therapies that are effective in one type of cancer are likely to demonstrate efficacy against additional types of cancer. On each additional approval, a company has the potential to increase revenues exponentially.

### **OVARIAN CANCER**

Ovarian cancer is the 5<sup>th</sup> leading cause of cancer related deaths among women. There are around 20,000 patients diagnosed per year in the US and 12,500 in Europe. Oasmia has a partnership deal with Medison Pharma for Turkey and Israel. Israel has one of the highest incidences of ovarian cancer in the world due to the prevalence of the BRCA 1 and 2 gene populations in Israel. These genes have been linked with a high risk of ovarian and breast cancers. Ovarian cancer has subtle symptoms and poor screening options. As a result, 75% of tumors are diagnosed very late in stage III or IV. These late stage tumors have a very poor prognosis, which leads to very high mortality rates.

### **COMPETITION FOR THE OVARIAN CANCER MARKET**

#### **Approved Therapies**

The current gold standard of treatment for ovarian cancer is paclitaxel and either cisplatin or carboplatin. This is a very effective treatment, but the major downside is the delivery of paclitaxel in Cremaphor EL. In addition to the health risks, paclitaxel requires premedication a three hour IV infusion. Paclical, on the other hand, requires no premedication and only a one hour infusion time. With no additional efficacy benefit, this fact alone would be enough to make Paclical the preferred choice of both doctors and patients. In addition, insurance companies are likely to reimburse a premium for Paclical as it will create cost savings over paclitaxel.

Oasmia has completed interim analysis of the Phase III study that demonstrates clearly that Paclical is safe and at least as effective as paclitaxel. It is likely that Paclical will have a greater efficacy than paclitaxel for three reasons. First, the formulation allows better dosing and more uniform delivery to the tumor site. This is likely to be more effective in killing tumor cells. Second, fewer patients will stop treatment or reduce the delivered dose due to allergic reactions or other adverse events. And finally, Cremaphor EL is suspected to be a factor in tumors acquiring resistance to paclitaxel and either cisplatin or carboplatin. Thus by delivering paclitaxel without the need for Cremaphor EL, Paclical may lead to decreased rates of resistance.

#### **Therapies in Clinical Trials**

There are a number of therapies in Phase III clinical trials for ovarian cancer. These therapies will seek approval and commercialization within the next one to two years. However, the majority of these drugs target either angiogenesis, the growth of new blood vessels, or are immunoactivators, which attempt to jump start the body's own immune system to attack and kill tumor cells. These drugs therefore have very different mechanisms of action to Paclical, a cytostatic that prevents cell division. Anti-angionenics and immunoactivators would likely be used either in conjunction with Paclical for first line therapies, or for resistant tumors. Therefore these therapies will not compete against Paclical for the same patients.

### Drugs in FDA Phase III Clinical Trials for Ovarian Cancer

Company	Product	Mechanism of Action
Roche	Avastin	Angiogenesis
GlaxoSmithKline	Pazopanib	Angiogenesis
Sanofi Aventis	Afibercept	Angiogenesis
Amgen	AMG386	Angiogenesis
Boehringer Ingelheim	BIBF1120	Angiogenesis
Schering Plough	SCH-58500	Immunoactivation
Morphotek	MORAb-003	Immunoactivation
Menarini	Abagovomab	Immunoactivation
Celgene	Abraxane*	Cytostatic
Endocyte	EC145	Cytostatic
BioNumerik	Karenitecin	Cytostatic

\* Abraxane is in Phase II trials

There are, however, three cytostatics in clinical trials which have the same mechanism of action as Paclical: Abraxane, EC145, and Karenitecin.

Abraxane is the only other conjugate of paclitaxel on the market. It was approved for breast cancer in 2005. It avoids the solubility problems of paclitaxel by binding the drug to albumin, a protein found in human blood. The product is now in development for other types of cancer including lung and ovarian cancer. The product is in Phase II clinical trials for ovarian cancer, but is noteworthy for its similarity to Paclical. Abraxane is made from human blood products and therefore carries a very small risk of transmitting viruses. The risk is small and mitigated by controls in the drug manufacturing process, but can never be fully eliminated. Therefore, all other aspects being equal, Paclical is superior to Abraxane. In addition, as Paclical has orphan drug designation in ovarian cancer with both the FDA and EMA. This will grant Oasmia seven years of market exclusivity in the US and ten in Europe. Because Abraxane is so similar to Paclical, Abraxane would have to demonstrate clear superiority to Paclical in order to gain an approval in this indication.

Endocyte's product, EC145 is in Phase III clinical trials for ovarian cancer. Like Paclical, EC145 is a drug conjugate. It binds to the Folate receptor, which is over expressed on some tumors and delivers a vinca alkaloid, a cytostatic that prevents cell division and ultimately kills the cancer cell. EC145 may eventually compete with Paclical as a first line treatment. However, the current studies are in platinum resistant ovarian cancer. These are the tumors that have previously been treated with paclitaxel and carboplatin or cisplatin and have become resistant. As these tumors are already resistant, the patients are not eligible for treatment with Paclical. EC145 will require further clinical studies to gain an approval as a first line treatment. With Paclical's orphan drug status, EC145, like Abraxane, would need to demonstrate clear superiority over Paclical. We would anticipate Endocyte preferring indications with greater patient numbers rather than attempting to compete with another orphan drug in first line ovarian cancer.

Like EC145, Karenitecin is in trials for platinum resistant ovarian cancer. Thus it would not compete directly with Paclical. Additionally, BioNumerik's trial commenced in 2008 and is still listed as recruiting patients. The company has not published press releases since the beginning of 2010. It appears unlikely the company will be able to fully enroll the trial, gain approval, and launch the product successfully on the market.

## ADDITIONAL INDICATIONS

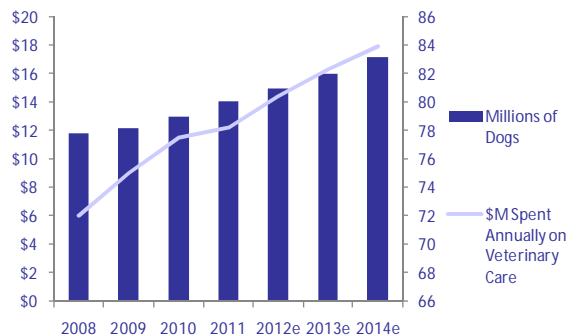
In addition to ovarian cancer, paclitaxel is approved for breast and lung cancer and AIDS related Kaposi sarcoma. Breast and lung cancer are each about ten times as prevalent as ovarian cancer. We would anticipate the company seeking additional approvals. Further clinical trials would be required, but revenue potential would grow exponentially with each indication. If all approvals are sought and granted, Paclical could easily reach blockbuster status (annual sales > \$1m).

## 7.2. Animal Health

### COMPANION ANIMALS AND VETERINARY SPENDING

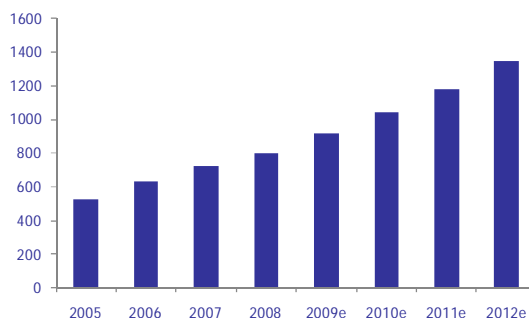
The number of companion animals is growing in the US, Europe and Japan. There are an estimated 78.2M dogs in the US alone. This number has grown an average of 2.8% annually since 2008. Additionally, spending on pets continues to increase as well. Spending on veterinary care has increased at an average rate of 6.4% since 2008. These trends have occurred even in spite of the challenging economic conditions over the past few years. The growth rate of veterinary spending is more than double that of companion dogs. This suggests that the major driver of growth is an increase in the cost of care per animal. Veterinarians are offering increasingly sophisticated treatment options for pets and pet owners are less willing to euthanize pets suffering for treatable conditions.

#### Number of Companion Dogs and Annual Veterinary Care Spending in US



As a result of the rising cost of veterinary care, pet owners are turning progressively more towards pet insurance. In some European countries as many as 50% of pet owners have insurance policies for their companion animals. Though penetration in the US remains low, the number of pet insurance policies in the US grew at an annual rate of 17% between 2005 and 2008. This trend is likely to continue as more veterinaries offer expensive diagnostic and treatment modalities once reserved for human medicine.

#### Number of Pet Insurance Policies in the US





An increase in pet insurance policies will widen the market for canine oncology treatments. Some pet owners will always opt for expensive treatments for their companion animals, but the option of having these treatments reimbursed by insurance and not causing out of pocket expenses makes this much more likely.

### CANINE ONCOLOGY

Cancer is the leading cause of death in dogs. One in four dogs will develop a tumor in its lifetime. The mortality rate for cancer is 23% of all dogs and 45% for dogs older than ten years. One in 4 dogs will develop a tumor in its lifetime and skin tumors are the most common types. Previously dogs were treated only by euthanasia. However, increasing numbers of canine oncology specialists and sophisticated diagnostic and imaging modalities are leading to a greater willingness on behalf of dog owners to treat cancers.

**Number of Dogs with Treatable Cancers ('000)**

	US	Europe	Japan	Total
Total Dogs	78,200	56,000	9,400	143,600
Dogs with cancer	1,095	784	132	2,010
Mastocytoma	230	165	28	422
Squamous Cell Carcinoma	115	82	14	211
Lymphoma	296	212	36	543

#### Mastocytoma and Squamous Cell Carcinoma

Canine mastocytoma makes up 7-21% of canine skin tumors. Of insured dogs in the UK in 2008, mastocytoma occurred in 129 per 100,000 dogs. Some breeds have a greater predisposition to the tumors. Boxers and Boston Terriers have the greatest incidences. Boxers have a 16.7% risk of developing mastocytoma.

Mastocytoma is usually a single tumor, but in up to 25% of dogs it manifests as multiple tumors. The tumors are present on the skin, but can also be present in other epithelial cells – in the mouth, esophagus, lining of the gastrointestinal tract, or around the eyes. The tumors can metastasize and spread, most often to the lymph nodes. Many tumors are treated with surgery, but this can be complicated as the tumors release substances that can delay wound healing and it is possible that not all tumor cells are removed. Gastrointestinal ulceration is common in dogs with mastocytoma. Even after surgery, the tumor recurs in up to 54% of dogs. Squamous cell carcinoma is the second most common type of skin cancer in dogs. In the absence of other available treatments, these tumors are usually treated with either surgery or off label human medicine treatments.

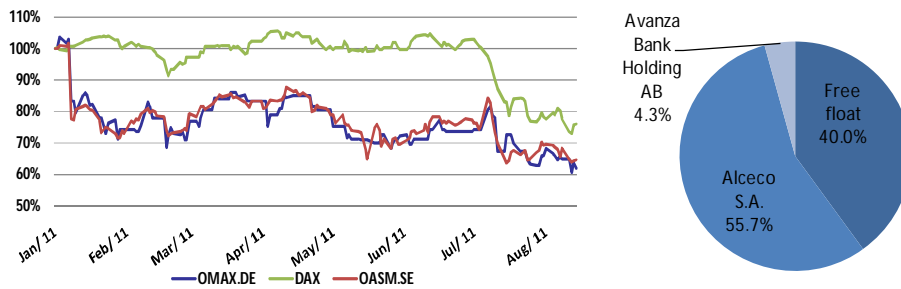
#### Lymphoma

Lymphoma is the most common hematologic neoplasm in dogs. Even aggressive treatment often fails to improve survival greater than 12 months. These dogs are often treated with off-label human medicines, radiation, or even bone marrow transplant. Docecal will be the first animal health treatment offered for canine lymphoma.

### COMPETING THERAPIES

There are three therapies currently on the market or seeking approval for canine oncology indications. Palladia (Pfizer) and Masivet/Kinavet (AB Sciences) both have approvals for canine mast cell tumor. Both of these therapies must be continued over the life of the dog. In contrast, Paccal Vet will require 4 monthly infusions. This represents a great advantage over therapies on the market.

## 8. OWNERSHIP AND SHARE PRICE DEVELOPMENT



Oasmia Pharmaceutical has a 40% free float. It is 55.7% held by its main shareholder, Alceco S.A., based in Luxemburg. The company has a dual listing on the Nasdaq OMX and the Frankfurt Stock Exchange. The company listed on the Frankfurt Stock Exchange in January, 2011 in order to ease its access to a wider base of investors. Trading volumes have been very low in Frankfurt due to lack of investor awareness. The two shares trade largely in line with each other, but there are some fluctuations resulting from exchange rate fluctuations and the low trading volumes in Frankfurt.

The share has been sliding downwards over the course of the year. Development stage biopharmaceutical shares are often characterized by periods of low volumes and downward trends in between periods of news flow. We anticipate an increase in volume, and correspondingly in the efficiency of the share as the company undertakes a more intensive communication strategy with German investors. In the near term the share price will be boosted on news flow related to regulatory approval of Paccal Vet and EMA submission of Paclical filing. Additional news flow related to partnership deals and the completion of the Phase III Paclical trial will boost share price over the coming year.

There remains a risk that the company will need to pull funds from the SEDA it has in place. Many development stage biopharmaceutical companies use similar equity instruments as bridge funding while closing partnership deals. This can often cause share price volatility as a proportion of these shares are released on the market. This volatility is often more pronounced when trading volumes are low. Oasmia will need to effectively boost trading volumes and time any pulled tranches appropriately in order to minimize the effect the SEDA might have on the share price. However, movements in share price created by SEDA tranches are often temporary jumps and have little impact on the underlying value of the company.

## 9. FINANCIAL STATEMENTS

### 9.1. Income Statement

Profit and Loss - OASMIA PHARMACEUTICALS AB				
In €M	Year End (30.4)			
	2008	2009	2010	2011
<b>Revenue</b>	<b>7.8</b>	<b>8.7</b>	<b>3.4</b>	<b>0.0</b>
Cost of Sales	-5.0	-6.2	-2.1	-1.8
Gross Profit	3.9	6.5	10.2	7.7
External Opex	-5.0	-4.1	-8.2	-10.2
Employee Costs	-2.2	-2.8	-3.2	-4.1
Impairment Charges	-1.9	-0.4	-0.4	-0.5
Other Operating Expenses	-0.3	-0.0	-0.0	-0.0
Other Income	0.0	0.0	0.0	0.0
<b>EBIT</b>	<b>-5.5</b>	<b>-0.8</b>	<b>-1.6</b>	<b>-7.1</b>
Financial Income	0.1	0.2	0.0	0.1
Financial Expenses	-0.1	-0.0	-0.3	-0.2
<b>EBT</b>	<b>-5.5</b>	<b>-0.7</b>	<b>-1.9</b>	<b>-7.2</b>
Income Tax Expense	0.0	-0.0	0.0	-0.0
Profit attributable to parent company	0.0	-0.1	0.0	0.0
Attributable to Minority Interests	0.0	-0.6	0.0	0.0
<b>Profit for the Year</b>	<b>-5.53</b>	<b>-0.71</b>	<b>-1.87</b>	<b>-7.25</b>
Earnings per Share	0.00	0.00	0.00	0.00
<b>Profit and Loss (Growth)</b>				
<b>Revenue</b>	<b>11.5%</b>	<b>-61.3%</b>	<b>-99.7%</b>	
Cost of Sales	24.9%	-66.7%	-14.4%	
Gross Profit	65.6%	57.3%	-24.3%	
Sales and Marketing Costs	-17.6%	99.2%	24.3%	
Administrative Costs	27.1%	14.6%	27.1%	
Research and Development Costs	-81.8%	13.3%	29.4%	
Other operating expenses	-99.7%	655.6%	95.6%	
Other operating income	244.6%	-100.0%		
<b>Operating Profit</b>	<b>-85.7%</b>	<b>109.1%</b>	<b>330.1%</b>	
Interest Income/Expense	216.9%	-71.9%	-	
Financial Income/Expense	-	-	-16.3%	
Foreign Currency Exchange Gains/Losses	-100.0%	-	-	
<b>Profit Before Tax</b>	<b>-87.9%</b>	<b>179.5%</b>	<b>286.7%</b>	
Income Tax Expense		-100.0%		
Profit for the Year		-100.0%		
Attributable to Minority Interests		-100.0%		
<b>Profit for the Year</b>	<b>-87.2%</b>	<b>164.9%</b>		
Earnings per Share				
<b>Profit and Loss (Percentage of Revenue)</b>				
<b>Revenue</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
Cost of Sales	-63.7%	-79.5%	-26.5%	-22.7%
Gross Profit	49.9%	82.7%	130.1%	98.4%
Sales and Marketing Costs	-63.7%	-52.5%	-104.6%	-130.0%
Administrative Costs	-28.4%	-36.1%	-41.3%	-52.5%
Research and Development Costs	-24.6%	-4.5%	-5.1%	-6.6%
Other operating expenses	-3.8%	0.0%	-0.1%	-0.2%
Other operating income	0.1%	0.3%	0.0%	0.4%
<b>Operating Profit</b>	<b>-70.5%</b>	<b>-10.1%</b>	<b>-21.0%</b>	<b>-90.4%</b>
Interest Income/Expense	0.6%	2.1%	0.6%	0.7%
Financial Income/Expense	-0.9%	-0.6%	-3.5%	-2.9%
Foreign Currency Exchange Gains/Losses	-12.8%	0.0%	12.8%	25.6%
<b>Profit Before Tax</b>	<b>-70.8%</b>	<b>-8.6%</b>	<b>-24.0%</b>	<b>-92.7%</b>
Income Tax Expense	0.0%	-0.5%	0.0%	0.0%
Profit for the Year	0.0%	-1.5%	0.0%	0.0%
Attributable to Minority Interests	0.0%	-7.5%	0.0%	0.0%
<b>Profit for the Year</b>	<b>-12.8%</b>	<b>0.0%</b>	<b>12.8%</b>	<b>25.6%</b>
Earnings per Share	-70.8%	-9.0%	-24.0%	-92.7%

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## 9.2. Balance Sheet

### Balance Sheet - OASMIA PHARMACEUTICALS AB

In €M	Year End (30.4)			
	2008	2009	2010	2011
<b>Assets</b>				
<u>Current Assets</u>				
<i>Inventories</i>	2.1	0.3	0.0	0.0
<i>Trade receivables</i>	0.5	0.3	0.0	0.0
<i>Derivative Instruments</i>	0.0	0.0	0.0	0.0
<i>Other current receivables</i>	0.1	0.1	0.2	0.2
<i>Prepaid Expenses and Accrued Income</i>	0.2	0.2	0.3	0.3
<i>Cash and cash equivalents</i>	1.2	0.1	0.6	5.8
<b>Total Current Assets</b>	<b>4.0</b>	<b>1.0</b>	<b>1.1</b>	<b>6.3</b>
<u>Non-Current Assets</u>				
<i>Property, Plant and Equipment</i>	2.1	2.2	2.3	3.0
<i>Capitalized Development Costs</i>	2.7	6.7	15.7	25.3
<i>Other Intangible Assets</i>	0.9	0.9	0.9	1.0
<i>Financial Assets</i>	0.0	0.0	0.0	0.0
<b>Total Non Current Assets</b>	<b>5.8</b>	<b>9.8</b>	<b>18.9</b>	<b>29.4</b>
<b>Total Assets</b>	<b>9.8</b>	<b>10.8</b>	<b>20.0</b>	<b>35.7</b>
<u>Equity</u>				
<i>Issued Capital</i>	0.4	0.4	0.4	0.6
<i>Additional Paid-in Capital</i>	10.7	11.1	21.9	46.1
<i>Accumulated Deficit</i>	-3.8	-4.6	-6.5	-13.9
<b>Total Equity</b>	<b>7.2</b>	<b>6.8</b>	<b>15.8</b>	<b>32.8</b>
<u>Non-Current Liabilities</u>				
<i>Long-Term Borrowings</i>	0.7	0.0	1.7	1.7
<i>Other Non-Current Liabilities</i>	0.0	0.0	0.0	0.0
<i>Deferred Tax Liabilities</i>	0.0	0.0	0.0	0.0
<b>Total Non-Current Liabilities</b>	<b>0.7</b>	<b>0.0</b>	<b>1.7</b>	<b>1.7</b>
<u>Current Liabilities</u>				
<i>Liabilities to Credit Institutions</i>	0.6	0.8	0.5	0.0
<i>Short Term Borrowings</i>	0.3	2.2	1.2	0.0
<i>Trade Payables</i>	0.4	0.3	0.2	0.4
<i>Other Current Liabilities</i>	0.2	0.2	0.1	0.2
<i>Prepaid Expenses and Accrued Income</i>	0.3	0.5	0.5	0.6
<b>Total Current Liabilities</b>	<b>1.8</b>	<b>4.0</b>	<b>2.5</b>	<b>1.2</b>
<b>Total Equity and Liabilities</b>	<b>9.8</b>	<b>10.8</b>	<b>20.0</b>	<b>35.7</b>

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### 9.3. Cash Flow Statement

Cash Flow Statement - OASMIA PHARMACEUTICALS AB				
In €M	Year End (30.4)			
	2008	2009	2010	2011
<b>Cash Flows from Operating Activities</b>				
EBIT	-0.5	-0.8	-1.7	-7.2
Depreciation and Amortisation	0.3	0.4	0.4	0.5
Impairment of Inventory	0.0	0.1	0.0	0.0
Disposals of Intangible Assets	0.0	0.0	0.0	0.0
Interest Received	0.1	0.1	0.0	0.1
Interest Paid	-0.1	-0.2	-0.2	-0.2
Cash Flow from Operations Before Changes in Working Capital	-0.3	-0.4	-1.4	-6.7
Changes in Inventories	-0.1	1.8	0.3	0.0
Changes in Trade Receivables	0.0	0.2	0.3	0.0
Changes in Other Current Receivables	0.0	0.0	-0.2	0.0
Changes in Trade Payables	-0.1	-0.1	-0.1	0.2
Changes in Current Liabilities	0.1	0.2	-0.1	0.2
Cash Flow from Operations	-0.3	1.6	-1.3	-6.4
Investments in Intangible Fixed Assets	-1.2	-4.07	-9.12	-9.9
Investments in Property, Plant and Equipment	-0.2	-0.3	-0.4	-1.2
Investments in Financial Assets	0.0	0.0	0.0	0.0
Cash Flows from Investing Activities	-1.4	-4.4	-9.5	-11.0
Increase in Liabilities to Credit Institutions	0.0	0.0	0.0	0.0
	0.3	0.2	-0.3	-0.5
<b>Changes in Long Term Liabilities</b>	<b>0.1</b>	<b>1.5</b>	<b>3.9</b>	<b>6.6</b>
Additional Paid in Capital	0.0	0.0	8.3	18.8
Share Issue Expenses	0.0	0.0	-0.6	-2.3
Cash Flows from Financing Activities	0.4	1.8	11.3	22.6
Cash Flows for the Period	-1.3	-1.0	0.5	5.2
<b>Cash and Cash Equivalents Brought Forward</b>	<b>2.5</b>	<b>1.2</b>	<b>0.1</b>	<b>0.6</b>
Cash and Cash Equivalents Carried Forward	<b>1.2</b>	<b>0.1</b>	<b>0.6</b>	<b>5.8</b>

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